Letter to the Editor

6th February 2003

Sir,

As the official journal of the World Federation of Interventional and Therapeutic Neuroradiology, it was not made clear in the editorial by the editor-in-chief in the December issue [1] whether the views expressed were those of the Federation or his personal view, I presume the latter.

I am concerned that the credibility of Interventional Neuroradiology as specialty in the wider medical community will be undermined if the views expressed are seen as a statement of the World Federation policy or even the views of a majority of its membership. The views reflect an attitude towards a scientific methodology (the randomised trial) at variance with that which is widely accepted by the rest of the clinical medical community.

The fact that more than 100,000 aneurysms have been treated by coiling in the last ten years, cannot be unequivocally accepted as evidence of safety and effectiveness.

Despite the International Subarachnoid Aneurysm Trial (ISAT) [2] starting in 1994, only two years after the introduction of the GDC device in Europe, it took nearly eight years to recruit the 2000 plus patients required to achieve the primary objective. Had those expert centres the editor cites decided to participate in the study then the answer is likely to have been achieved much sooner.

One of the reviewers of the paper submitted to the Lancet, a highly respected European Professor of Neurology with many years experience of managing subarachnoid haemorrhage and of clinical trials, said in his review "without this study we would be in the appalling situation of not knowing what represented the best management for ruptured cerebral aneurysms"; the corollary is that many patients in many centres would continue to receive a higher risk treatment.

Randomised trials always represent a balance between individual ethics and community ethics. It is a fact of 21st century medical life that *where possible* best evidence should be gained from adequate sized randomised trials. For those willing to study the subject there are countless examples throughout the history of medical practice where expert advice and opinion have been subsequently shown to be incorrect. It is for this very reason and the protection of society as a whole, why randomised evidence, *when it is possible*, is so essential.

The value of this route is that whilst a single interventionist or centre can make a difference to only the relatively few patients referred to that centre, if such treatment can be generalised and available to a wider population then many more patients benefit. When evidence, such as is presented by the findings of ISAT, gained from many centres and many interventionists and surgeons that seven patients in every 100 with ruptured aneurysm treated by coiling as opposed to surgery will survive free of disability, then it is applicable to many thousands of patients in many countries over many years. It is only evidence such as this that leads to a widespread and significant change in practice and reflects what is (or should be) available to all patients in Europe and in other developed countries not just the few patients lucky enough to be admitted to the expert centres.

Those who supported and had confidence in the study should be proud of what was achieved and especially the patients and their relatives who agreed to participate. We as investigators are grateful for the enormous support and encouragement we have received from the vast majority of our colleagues, not only in interventional neuroradiology but in neurosurgery and the allied specialities.

This achievement, of many dedicated people, should be seen as a coming of age and maturing of our speciality.

References

1 P. Lasjaunias: ISAT trial EBM Rescues Common Sense. Is Experience a Romantic Concept? Interventional Neuroradiology 8: 337-339, 2002.

2 International Subarachnoid Aneurysm Trial (ISAT) of neurosurgical clipping versus endovascular coiling in 2143 patients with ruptured intracranial aneurysms: a randomised trial. International subarachnoid haemorrhage collaborative group, Lancet: 360, 1267-1274, 2002.

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November 28th, 2002

I read with great interest the comment of Prof. G. Rodesch about the use of the new embolic agent (Glubran II) reported in the paper by Prof. M. Leonardi.

Prof. Rodesch was concerned about the abrupt getaway from Histoacryl, considered the "classic" cyanoacrylic glue, which has been used with good results for the last 20-25 years.

I agree with Prof. Rodesch, also on the basis of my personal experience, that Histoacryl in skilled hands is a very useful embolic agent; nevertheless, not only the Braun Company did not declare that Histoacryl could be used as an embolic agent for the endovascular treatment of vascular malformation, but did not even authorize its endovascular administration, in spite of the favourable opinion of many Neuroradiologists and Neuroradiological Societies.

More recently, the Italian Ministry of Health has officially prohibited the use of Histoacryl as an embolic agent for the endovascular treatment of vascular malformations, while other agents (Glubran II), which have been officially developed for this purpose and carry the "CE" appointment, are allowed.

The decision to get away from Histoacryl, rejecting a long positive experience, to start with a new similar, but little known, agent has not been an easy one; however, at least for Italian Interventional Neuroradiologists (I don't know the situation in other European Countries) a different choice was not possible.

Moreover, the initial experiences with Glubran II in many italian centres are favourable.

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